Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

19 December 2019*

(Plant protection products — Active substance 8-hydroxyquinoline — Request for amendment of the conditions of approval — Procedure for harmonised classification and labelling — Right to be heard — Legitimate expectations — Manifest error of assessment)

In Case T-67/18,

Probelte, SA, established in Murcia (Spain), represented by C. Mereu and S. Saez Moreno, lawyers,

applicant,

v

European Commission, represented by A. Lewis, G. Koleva and I. Naglis, acting as Agents,

defendant,

APPLICATION based on Article 263 TFEU seeking annulment of Commission Implementing Regulation (EU) 2017/2065 of 13 November 2017 confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation (EU) No 540/2011 and modifying Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution (OJ 2017 L 295, p. 40),

THE GENERAL COURT (Fifth Chamber),

composed of D. Gratsias (Rapporteur), President, K. Kowalik-Bańczyk and R. Frendo, Judges,

Registrar: E. Artemiou, Administrator,

having regard to the written part of the procedure and further to the hearing on 21 June 2019,

gives the following

Judgment

Background to the dispute

1 The applicant, Probelte, SA, produces and sells plant protection products made using the active substance 8-hydroxyquinoline.

* Language of the case: English.

2 That active substance was approved for a duration of 10 years under Commission Implementing Regulation (EU) No 993/2011 of 6 October 2011 approving the active substance 8-hydroxyquinoline, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ 2011 L 263, p. 1).

3 According to Annex I to Implementing Regulation No 993/2011, which lays down the conditions of approval of 8-hydroxyquinoline, only uses as fungicide and bactericide in greenhouses may be authorised. Those conditions are now set out in Row 18 of Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 Implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ 2011 L 153, p. 1).

4 On 31 January 2014, the applicant, on the basis of Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ 2009 L 309, p. 1), made a request for amendment of the conditions of approval of 8-hydroxyquinoline with a view to having the restriction on its use in greenhouses lifted. That request was made to the competent Spanish authority, as the Kingdom of Spain was the designated rapporteur Member State for that active substance under Annex I to Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 (OJ 2002 L 224, p. 23).

5 Furthermore, in September 2014, the Kingdom of Spain submitted to the European Chemicals Agency (ECHA) a report relating to a proposal for a harmonised classification and labelling of 8-hydroxyquinoline. The proposal was introduced in accordance with Article 37 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1). According to the conclusion set out in paragraph 4.11.6 of the report in question, 8-hydroxyquinoline was to be classified as toxic for reproduction category 2, that is to say, as a substance suspected of being toxic for human reproduction.

6 It is apparent from what is set out in paragraphs 4 and 5 above that two procedures were initiated, one for the amendment of the conditions of approval of 8-hydroxyquinoline with a view to having the restriction on its use in greenhouses lifted and the other concerning the harmonised classification and labelling of that active substance.

Procedure for harmonised classification and labelling of 8-hydroxyquinoline

7 By an opinion of 5 June 2015, issued following the public consultation during which the applicant submitted its observations, ECHA's Risk Assessment Committee stated that it was in favour of classifying 8-hydroxyquinoline as a toxic substance for reproduction category 1B, on the basis, in particular, of a study which had shown malformation (omphalocele) in rabbits.

8 On 10 March 2016, the applicant requested the competent Spanish authority's permission, inter alia, to carry out new studies on developmental toxicity in rabbits and to complete the observations made in a 2006 study. By letter of 14 March 2016, the competent Spanish authority acceded to that request. That authority drew the applicant's attention, in that regard, to Article 62(1) of Regulation No 1107/2009, pursuant to which testing on vertebrate animals may be undertaken only where no other methods are available.

9 On 14 December 2016, the applicant asked ECHA for clarification on the interaction between the procedure for classification and labelling, on the one hand, and the procedure for amendment of the conditions of approval of 8-hydroxyquinoline, on the other. The applicant also asked ECHA to set out for it the procedure to be followed for the purposes of triggering a new assessment by ECHA's Risk Assessment Committee, in the light of the new studies which, at that stage, had not yet been completed.

10 On 9 January 2017, ECHA informed the applicant that the European Commission had already taken a decision, not yet published, on the harmonised classification and labelling of 8-hydroxyquinoline and that, therefore, a new request for harmonised classification had to be introduced by the competent Spanish authority, in accordance with Article 37 of Regulation No 1272/2008, in order that the classification of the substance as a toxic substance for reproduction category 1B could be re-examined by ECHA's Risk Assessment Committee.

11 On 20 January 2017, the applicant requested the competent Spanish authority to propose to ECHA the amendment of the harmonised classification and labelling of 8-hydroxyquinoline. On 4 April 2017, that authority asked the applicant to inform it of the date on which the final results of the studies, referred to in paragraph 8 above, would be available. On 19 May 2017, the applicant replied that the new classification proposal file and the final results in question would be available at the end of May 2017.

12 On 4 May 2017, the Commission adopted Regulation (EU) 2017/776 amending, for the purposes of its adaptation to technical and scientific progress, Regulation No 1272/2008 (OJ 2017 L 116, p. 1). Under Article 1 of that regulation, Annex VI to Regulation No 1272/2008 was amended to include, inter alia, 8-hydroxyquinoline in the harmonised classification and labelling table. It is clear from that inclusion that 8-hydroxyquinoline is now classified, inter alia, as toxic for reproduction category 1B.

13 On 31 May 2017, the applicant sent to the Commission the documentation relating to the studies referred to in paragraph 8 above, forwarded on the same day to the competent Spanish authority for the purposes of reopening the harmonised classification and labelling procedure.

14 By letter of 28 September 2017, the competent Spanish authority explained to the applicant the reasons why it considered that the evidence from the studies in question was not sufficient to call into question the harmonised classification and labelling in force and that they therefore did not justify a new proposal in that regard.

Procedure for amendment of the conditions of approval of 8-hydroxyquinoline

15 In the meantime, following the applicant's request for amendment of the conditions of approval of 8-hydroxyquinoline, referred to in paragraph 4 above, the competent Spanish authority proposed to the European Food Safety Authority (EFSA), in accordance with Article 11 of Regulation No 1107/2009, the amendment of the conditions of approval of that active substance so that its outdoor use would be permitted from then onwards. To that end, the competent Spanish authority submitted to EFSA, on 25 March 2015, an addendum to the initial draft assessment report, which had served as the basis for the initial approval of that active substance.

16 EFSA sent the addendum to the Member States and to the applicant, and also made it publicly available, setting a period of 60 days for the submission of written observations.

17 By document dated 9 June 2015, the applicant submitted its observations on the addendum to the draft assessment report.

18 On 4 September 2015, EFSA asked the applicant to provide additional information within 90 days, in accordance with Article 12(3) of Regulation No 1107/2009. The applicant acceded to that request by letter of 3 December 2015.

19 On 2 May 2016, EFSA sent to the applicant its conclusions on the request for amendment of the conditions of approval of 8-hydroxyquinoline and requested the applicant to indicate any confidential information that should not be disclosed to the public. On 24 June 2016, the applicant shared its observations on those conclusions. In its conclusions, EFSA set out the assessment by ECHA's Risk Assessment Committee, according to which 8-hydroxyquinoline was to be classified as a toxic substance for reproduction category 1B (see paragraph 7 above). In addition, EFSA pointed out that 8-hydroxyquinoline has endocrine-disrupting properties, within the meaning of point 3.6.5 of Annex II to Regulation No 1107/2009.

20 In accordance with Article 13(1) of Regulation No 1107/2009, the Commission prepared an addendum to the review report provided for by that provision. It is apparent from that addendum that, in the view of the Commission, the safety requirements for outdoor use of 8-hydroxyquinoline had not been met on account of the two characteristics of that active substance referred to in paragraph 19 above. By email of 13 December 2016, the Commission invited the applicant to submit its comments on that addendum by 20 January 2017.

21 On 20 January 2017, the applicant disputed the Commission's conclusions and requested the postponement of any decision pending the results of the new studies referred to in paragraphs 8 and 11 above.

22 As mentioned in paragraph 13 above, on 31 May 2017 the applicant sent to the Commission the documentation relating to the studies in question, which was forwarded on the same day to the competent Spanish authority for the purposes of reopening the harmonised classification and labelling procedure.

23 On 2 June 2017, the Commission informed the applicant that it would be sending that information to the Member States in the context of the next meeting of the Standing Committee on Plants, Animals, Food and Feed, composed of the representatives of the Member States ('the Standing Committee').

24 The Commission submitted the addendum referred to in paragraph 20 above and a draft Implementing Regulation to the Standing Committee in order for it to make a decision on the request for amendment of the conditions of approval of 8-hydroxyquinoline, for discussion and vote at the meeting on 19 and 20 July 2017. The Standing Committee decided to postpone the vote.

25 The Commission re-submitted to the Standing Committee the addendum referred to in paragraph 20 above and the draft Implementing Regulation referred to in paragraph 24 above for discussion and vote at the meeting held on 6 October 2017.

26 On 13 November 2017, the Commission adopted Implementing Regulation (EU) 2017/2065 confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation No 540/2011 and modifying Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution (OJ 2017 L 295, p. 40; 'the contested Implementing Regulation').

27 The Commission states, in recital 6 of the contested Implementing Regulation, that, according to the opinion issued by ECHA's Risk Assessment Committee on the proposal for harmonised classification and labelling, 8-hydroxyquinoline should be classified as a toxic substance for reproduction category 1B (see paragraphs 5 to 7 above). Furthermore, recital 7 of the contested Implementing Regulation refers to EFSA's conclusion that some toxic effects were observed on endocrine organs (see paragraph 19 above).

28 In recitals 8 and 9 of the contested Implementing Regulation, the Commission refers to the addendum to the review report and to the draft Implementing Regulation examined at the meeting of the Standing Committee on 6 October 2017. The Commission adds that the applicant was given the opportunity to submit its observations (see paragraphs 20, 21, 24 and 25 above) and that they were examined in detail. According to recital 9 of the contested Implementing Regulation, those observations did not eliminate the concerns set out in paragraph 27 above.

29 In that context, first, the Commission concluded that it could not be expected that plant protection products containing 8-hydroxyquinoline satisfy in general the requirements laid down in Article 4 of Regulation No 1107/2009 unless the restrictions currently provided for that active substance are kept (recital 10 of the contested Implementing Regulation).

30 Second, the Commission took the view that the evaluation of the request for amendment of the conditions of approval of 8-hydroxyquinoline could not be regarded as a review of the approval of 8-hydroxyquinoline under Article 21 of Regulation No 1107/2009 (see paragraph 119 below), and that it was for that reason necessary for the conditions of approval of that active substance, as had been established under Regulation No 540/2011, to remain unchanged and to be confirmed (recital 11 of the contested Implementing Regulation).

31 Third, the Commission stated that, as a substance which was toxic for reproduction category 1B and had endocrine-disrupting properties, 8-hydroxyquinoline meets the conditions laid down in the sixth and seventh indents of point 4 of Annex II to Regulation No 1107/2009. That active substance therefore had to be included in the Annex to Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation No 1107/2009 (OJ 2015 L 67, p. 18) (recital 12 of the contested Implementing Regulation).

32 Article 1 of the contested Implementing Regulation provides that the conditions of approval of 8-hydroxyquinoline, as set out in Row 18 of Part B of the Annex to Implementing Regulation (EU) No 540/2011, are confirmed.

33 Under Article 2 of the contested Implementing Regulation, 8-hydroxyquinoline is inserted into the Annex to Implementing Regulation 2015/408 as a candidate for substitution.

Procedure and forms of order sought

34 By application lodged at the Registry of the General Court on 5 February 2018, the applicant brought the present action.

35 On 24 April 2018, the Commission lodged its defence.

36 The reply and the rejoinder were lodged, respectively, on 30 July 2018 and on 17 September 2018.

37 By letter of 17 September 2018, the parties were informed that the written part of the procedure had been closed and that they could request that a hearing be held under the conditions set out in Article 106 of the Rules of Procedure of the General Court. By letter of 26 September 2018, the applicant requested that a hearing be held.

38 On 27 May 2019, by a measure of organisation of procedure, the Court put a question for an oral answer at the hearing and requested the Commission to state whether the applicant had complied with EFSA's request of 4 September 2015 (see paragraph 18 above). The Commission replied to that question by letter of 7 June 2019.

39 The hearing was held on 21 June 2019. At the hearing, the Commission challenged the admissibility of the third plea in law (see paragraph 44 below).

40 The applicant claims that the Court should:

– annul the contested Implementing Regulation;

– order the Commission to pay the costs.

41 The Commission contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

Law

42 In support of its action, the applicant raises three pleas in law, alleging, first, infringement of its right to be heard and of the principle of the protection of legitimate expectations, second, a manifest error of assessment and, third, infringement of point 4 of Annex II to Regulation No 1107/2009.

43 It should be noted at the outset that the first two pleas in law concern both Article 1 of the contested Implementing Regulation, under which the Commission confirmed the conditions of approval of 8-hydroxyquinoline and, consequently, rejected the applicant's request for the amendment of those conditions, and Article 2 of that regulation, under which the Commission included 8-hydroxyquinoline in the list annexed to Implementing Regulation 2015/408 as a candidate for substitution. The third plea in law relates exclusively to Article 2 of the contested Implementing Regulation.

44 At the hearing, the Commission challenged, from the point of view of the applicant's standing to bring proceedings, the admissibility of the third plea in law, by which the applicant challenges the legality of Article 2 of the contested Implementing Regulation. However, given that the applicant challenges the legality of the latter provision also by the first two pleas in law, it is necessary to examine the admissibility of the action in its entirety, as admissibility can be examined by the EU judicature of its own motion.

Admissibility

45 Under the fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs of that article, institute proceedings against an act addressed to that person or which is of direct and individual concern to that person, and against a regulatory act which is of direct concern to that person and does not entail implementing measures.

46 The meaning of 'regulatory act' for the purposes of the fourth paragraph of Article 263 TFEU must be understood as covering all acts of general application apart from legislative acts (order of 6 September 2011, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, T-18/10, EU:T:2011:419, paragraph 56).

47 It should be noted at the outset that the applicant is not the addressee of the contested Implementing Regulation. In addition, as it constitutes an implementing act within the meaning of Article 291(4) TFEU, that regulation does not constitute a legislative act within the meaning of Article 289 TFEU.

48 Article 1 of the contested Implementing Regulation establishes a measure of general application concerning the conditions of approval of 8-hydroxyquinoline. Moreover, Article 2 of the contested Implementing Regulation establishes a measure of general application concerning the inclusion of 8-hydroxyquinoline in the list of candidates for substitution. Consequently, in the light of what has been stated in paragraphs 46 and 47 above, that regulation constitutes a regulatory act within the meaning of the fourth paragraph of Article 263 TFEU.

49 It is apparent from those findings that, under the fourth paragraph of Article 263 TFEU, the applicant may seek the annulment of the contested Implementing Regulation if it is directly concerned both by Article 1 and by Article 2 of that Implementing Regulation (see paragraphs 50 to 60 below). Moreover, the question as to whether recognition of the applicant's standing to bring an action for annulment of those provisions requires that it be directly concerned by those provisions depends, in turn, on whether the provisions in question entail implementing measures (see paragraphs 61 to 81 below).

Direct concern to the applicant

50 The condition that a natural or legal person must be directly concerned by the decision against which the action is brought, laid down in the fourth paragraph of Article 263 TFEU, requires two cumulative criteria to be met, namely, first, that the contested measure must directly affect the legal situation of the individual and, second, that it must leave no discretion to its addressees who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from the EU rules alone without the application of other intermediate rules (see judgment of 6 November 2018, *Scuola Elementare Maria Montessori* v *Commission*, *Commission* v *Scuola Elementare Maria Montessori* and *Commission* v *Ferracci*, C-622/16 P to C-624/16 P, EU:C:2018:873, paragraph 42 and the case-law cited).

– *Article 1 of the contested Implementing Regulation*

51 In that regard, it must be recalled that, under Article 1 of the contested Implementing Regulation, the Commission, after examining the substance, rejected the applicant's request for amendment of the conditions of approval of 8-hydroxyquinoline and thus confirmed the conditions attached to the initial approval of that active substance, carried out under Regulation No 993/2011. That refusal requires the Member States which have granted authorisations for plant protection products containing 8-hydroxyquinoline to continue to limit the use of those products in greenhouses and does not allow them any discretion in that regard. Consequently, Article 1 of the contested Implementing Regulation directly affects the applicant's legal situation as an undertaking which produces 8-hydroxyquinoline and plant protection products containing it, with the result that the applicant is directly concerned (see, to that effect, judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraphs 35 and 36).

– *Article 2 of the contested Implementing Regulation*

52 According to Article 24(1) of Regulation No 1107/2009, an active substance is to be approved as a candidate for substitution if it meets one or more of the additional criteria laid down in point 4 of Annex II to that regulation. The list of candidates for substitution is to be drawn up in accordance with Article 24(2) of Regulation No 1107/2009, according to which those substances are to be listed separately in a regulation. In the present case, it must be borne in mind that, under Article 2 of the contested Implementing Regulation, entitled 'Amendment to the Annex to Implementing Regulation … 2015/408', 8-hydroxyquinoline was included in the list, annexed to that regulation, of the candidates for substitution (see paragraphs 27 and 31 above).

53 As regards the legal effects arising from the inclusion of a substance on that list, first, it must be noted that, according to Article 24(1) of Regulation No 1107/2009, the approval of a candidate for substitution is renewable for a maximum period of 7 years, unlike the approval of other active substances, which may be renewed for a maximum period of 15 years, pursuant to Article 14(2) of that regulation. Therefore, by reason of the fact of including 8-hydroxyquinoline in the list annexed to Implementing Regulation 2015/408, as a candidate for substitution, the renewal of its approval could be granted for a maximum period of only 7 years and not for a longer maximum period, as would have been the case if that substance had not been included in that list (judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraph 49).

54 As regards the question of whether the contested Implementing Regulation leaves discretion to the addressees who have the task of implementing it, it must be observed that, admittedly, the effects of that regulation on the duration of the validity of the renewal of approval of 8-hydroxyquinoline will be deployed with respect to the applicant only by the possible adoption, on the basis of Article 20(1) of Regulation No 1107/2009, referred to in Article 24(2) of that regulation, of a Commission regulation renewing for a maximum period of 7 years the approval of that substance (judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraph 52).

55 However, what matters in the context of the examination as to whether the applicant is directly concerned, as an undertaking which produces 8-hydroxyquinoline and plant protection products containing it, under Article 2 of the contested Implementing Regulation, is that, from the time at which that regulation was adopted, the Commission became automatically bound by that Article 2 to the effect that any renewal of approval of 8-hydroxyquinoline may not exceed 7 years, in accordance with Article 24(1) of Regulation No 1107/2009.

56 Second, Article 2 of the contested Implementing Regulation has the effect of making plant protection products containing 8-hydroxyquinoline subject to the comparative assessment procedure laid down in Article 50 of Regulation No 1107/2009 and carried out during the assessment of any application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution. In the context of that study, the risks to health or the environment posed by the relevant plant protection product are compared with the risks of the same type associated with a replacement product or with a non-chemical method of pest prevention.

57 It is true that Member States bear the responsibility for performing that comparative assessment (judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraph 56). However, what matters in the context of the assessment of whether the applicant is directly concerned by Article 2 of the contested Implementing Regulation is that, as is apparent from Article 50 of Regulation No 1107/2009, the Member States are, subject to the strict conditions laid down in Article 50(3) of that regulation, automatically obliged to carry out that comparative evaluation when assessing any application for authorisation relating to a plant protection product containing an active substance approved as a candidate for substitution and have no discretion in that regard. That obligation, which, according to Article 3 of the contested Implementing Regulation, exists for applications for authorisation submitted after 4 April 2018, has a direct bearing on the legal rules applicable to requests for authorisation for plant protection products containing 8-hydroxyquinoline.

58 Third, with regard to the rules on mutual recognition, as between Member States, of marketing authorisations of plant protection products containing candidates for substitution, Article 41(2)(b) of Regulation No 1107/2009 provides that a Member State which receives, under the mutual recognition procedure, an application for marketing authorisation for plant protection products containing a candidate for substitution may authorise those plant protection products. By contrast, outside the other hypotheses covered by Article 41(2), and without prejudice to the application of Article 36(3) of that regulation, the Member State is required, under Article 41(1) of that regulation, to issue such an

authorisation in accordance with the conditions laid down in that latter provision (judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraph 60).

59 However, what matters in the context of the assessment of whether the applicant is directly concerned by Article 2 of the contested Implementing Regulation is that the inclusion of an active substance in the list of candidates for substitution automatically amends the legal rules applicable to mutual recognition of authorisations of plant protection products in the manner set out in paragraph 58 above.

60 It follows that, as an undertaking which produces 8-hydroxyquinoline and plant protection products containing it, the applicant is directly concerned, within the meaning of the fourth paragraph of Article 263 TFEU, by Article 2 of the contested Implementing Regulation.

Individual concern to the applicant

– *Article 1 of the contested Implementing Regulation*

61 Since Article 1 of the contested Implementing Regulation, after examination of the substance of the application submitted by the applicant, merely confirms the conditions of approval of 8-hydroxyquinoline, and therefore rejects that application, it does not entail implementing measures within the meaning of the fourth paragraph of Article 263 TFEU. It follows that, under Article 263 TFEU, the applicant's direct concern is sufficient to confer on it standing to bring proceedings for the annulment of Article 1 of the contested Implementing Regulation, without any individual concern being required for that purpose.

62 In any event, the applicant is individually concerned by Article 1 of the contested Implementing Regulation, within the meaning of Article 263 TFEU.

63 According to settled case-law, persons other than those to whom a decision is addressed may claim to be individually concerned, within the meaning of the fourth paragraph of Article 263 TFEU, only if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of those factors distinguishes them individually just as in the case of the person addressed by such a decision (judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraph 93 and the case-law cited).

64 The party making an application for approval or for amendment of the conditions of approval of an active substance, having submitted the dossier and participated in the assessment procedure, as did the applicant, is concerned by a measure rejecting the application at issue by reason of certain attributes which are peculiar to it and by reason of a factual situation which differentiates it from all other persons and distinguishes it individually within the meaning set out in paragraph 63 above (see, to that effect, judgment of 17 May 2018, *BASF Agro and Others* v *Commission*, T-584/13, EU:T:2018:279, paragraph 45 and the case-law cited).

– *Article 2 of the contested Implementing Regulation*

65 It has already been held that, according to Article 24(1), Article 41(1), Article 41(2)(b) and Article 50 of Regulation No 1107/2009, a regulation under which an active substance is included in the list of candidates for substitution entails implementing measures in the form of measures that will be adopted by the Commission or by the Member States in order to implement the specific rules

applicable to the substances in question and thus to establish the legal effects of that inclusion with regard to the applicant (see, to that effect, judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraphs 47 to 62, and 66).

66 It follows that the applicant must be individually concerned, within the meaning set out in paragraph 63 above, by Article 2 of the contested Implementing Regulation in order to be able to challenge its legality.

67 In that regard, it should be recalled that the fact that a person participates in the process by which an EU measure is adopted is such as to distinguish that person individually with regard to the measure in question where provision has been made under the relevant rules for procedural guarantees in favour of that person. Thus, where a provision of EU law requires that, for the purposes of adopting a decision, a procedure must be followed in respect of which a natural or legal person may assert rights, such as the right to be heard, the special legal position which that person enjoys has the effect of distinguishing him or her individually for the purposes of the fourth paragraph of Article 263 TFEU (order of 17 February 2009, *Galileo Lebensmittel* v *Commission*, C-483/07 P, EU:C:2009:95, paragraph 53; judgment of 2 March 2010, *Arcelor* v *Parliament and Council*, T-16/04, EU:T:2010:54, paragraph 119; and order of 7 September 2010, *Etimine and Etiproducts* v *Commission*, T-539/08, EU:T:2010:354, paragraph 109).

68 That is precisely the case here.

69 In particular, it is apparent from Article 7(1) of Regulation No 1107/2009 that the procedure for the approval of an active substance also applies with regard to requests for amendment of the conditions of approval of such a substance. As set out in paragraph 4 above, the procedure which led to the adoption of the contested Implementing Regulation was initiated following an application made by the applicant in accordance with Article 7 of Regulation No 1107/2009 for amendment of the conditions of approval of 8-hydroxyquinoline. Moreover, it is apparent from the first sentence of Article 24(2) of Regulation No 1107/2009 that Articles 4 to 21 of that regulation apply with regard to the assessment of whether an active substance is to be included in the list of candidates for substitution. It follows that that examination may be made in the context of an initial application for approval or, as in the present case, an application for amendment of the conditions of approval of an active substance (Articles 7 to 13 of Regulation No 1107/2009), but also in the context of a procedure for the renewal or review of approval of that substance (Articles 14 to 21 of Regulation No 1107/2009).

70 Consequently, the first sentence of Article 24(2) of Regulation No 1107/2009 is applicable for the purposes of the inclusion of 8-hydroxyquinoline in the list of candidates for substitution. As set out in greater detail in paragraphs 94, 95, 97 and 99 below, Article 12(1) and (2) and Article 13(1) of Regulation No 1107/2009, which are applicable, according to the first sentence of Article 24(2) of that regulation, for the purposes of the inclusion of an active substance in the list of candidates for substitution following the procedure initiated subsequent to an application for amendment of the conditions of approval of the substance in question, establish specific procedural rights in favour of the applicant.

71 As is apparent, moreover, from paragraphs 96, 100 and 101 below, those rights were, in fact, fully respected not only as regards the amendment of the conditions of approval of 8-hydroxyquinoline but also, in accordance with the first sentence of Article 24(2) of Regulation No 1107/2009, as regards the inclusion of that active substance on the list of candidates for substitution. In particular, it is apparent from Annexes A 12 to A 15 to the application (pages 534, 552, 558, 601 and 604 of the file) that the applicant was specifically invited, as a party submitting an application, to submit its observations on the information relating both to the toxicity for reproduction category 1B and to the endocrine-disrupting properties of 8-hydroxyquinoline, namely the two grounds underlying Article 2 of the contested Implementing Regulation (see paragraphs 27 and 31 above). The applicant was also requested to indicate any confidential information which should not be disclosed to the public.

72 In that context, the applicant is specifically mentioned in recitals 2 and 9 of the contested Implementing Regulation as an applicant undertaking which had initiated the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline and which, in that capacity, was specifically invited to submit its observations on the addendum to the review report regarding that active substance.

73 It follows that the applicant is individually concerned by Article 2 of the contested Implementing Regulation.

74 That conclusion is not brought into question by the reference made by the contested Implementing Regulation, in its second citation and in recital 12, to Article 80(7) of Regulation No 1107/2009.

75 According to Article 80(7) of Regulation No 1107/2009, 'by 14 December 2013, the Commission shall establish a list of substances included in Annex I to Directive [91/414] which satisfy the criteria set out in point 4 of Annex II to this Regulation and to which the provisions of Article 50 of this Regulation shall apply'. It is clear from the wording of that provision that, through it, the Commission was responsible for assessing the active substances already included in the list in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1), in order to determine which substances met the criteria set out in point 4 of Annex II to Regulation No 1107/2009 and which should therefore be included in the list of candidates for substitution.

76 That procedure resulted in the adoption of Implementing Regulation 2015/408, which contains an annex setting out the list of candidates for substitution. In that regard, it should be noted that 8-hydroxyquinoline was not included in the list of candidates for substitution set out in the annex to Implementing Regulation 2015/408 in its original version. As the applicant observed in that regard at the hearing, without being contradicted by the Commission on that point, 8-hydroxyquinoline had been assessed by the Commission in the course of the procedure which led to the adoption of Implementing Regulation 2015/408 and had not been regarded, on the basis of the information available at the time, as meeting the criteria set out in point 4 of Annex II to Regulation No 1107/2009.

77 It is only in the context of the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline, initiated by the applicant in accordance with Article 7 of Regulation No 1107/2009, that that active substance was included in the list of candidates for substitution, in accordance with Article 24 of that regulation and on the basis of information subsequent to that taken into account when that substance was assessed in the context of the adoption of Implementing Regulation 2015/408 (see paragraphs 7, 19 and 69 to 72 above).

78 It is true that Article 80(7) of Regulation No 1107/2009, pursuant to which Implementing Regulation 2015/408 was adopted in its original version, did not confer any right on undertakings which had applied for approval of active substances that the Commission was required to assess, under that same provision, for the purposes of possible inclusion in the list of candidates for substitution (judgment of 13 March 2018, *European Union Copper Task Force* v *Commission*, C-384/16 P, EU:C:2018:176, paragraphs 88 and 89, and order of 27 April 2016, *European Union Copper Task Force* v *Commission*, T-310/15, not published, EU:T:2016:265, paragraph 22). However, Article 24(2) of Regulation No 1107/2009, which applies to the present case (see paragraph 70 above), confers procedural rights on the applicant which render it individually concerned within the meaning of the fourth paragraph of Article 263 TFEU. It follows that the judgment of 13 March 2018, *European Union Copper Task Force* v *Commission* (C-384/16 P, EU:C:2018:176, paragraphs 87 to 104), under which the Court of Justice held that operators which had requested approval of the substances included in the list annexed to the original version of Implementing Regulation 2015/408 were not individually concerned by that regulation, does not call into question the conclusion set out in paragraph 73 above.

79 In that context, the reference in the second citation of the contested Implementing Regulation and in its recital 12 to Article 80(7) of Regulation No 1107/2009 must be understood as setting out the reasons why the Commission established a single list of candidates for substitution, annexed to Implementing Regulation 2015/408. As stated in that recital 12, that list contains both, first, active substances included in the list in Annex I to Directive 91/414 and, second, active substances approved on the basis of the transitional provisions of Article 80(1) of Regulation No 1107/2009. Furthermore, that list is intended to group together all the active substances in those two categories which were found to meet the criteria set out in point 4 of Annex II to that regulation, whether that finding was made in the context of the procedure laid down in Article 80(7) of Regulation No 1107/2009 or in the course of a subsequent procedure for the approval, amendment of the conditions of approval, or the renewal or review of the approval of those substances. As is apparent from the second paragraph of Article 1 of Implementing Regulation 2015/408, the Commission is required to gather all active substances coming within the abovementioned two categories into a single list of candidates for substitution.

80 Moreover, Article 24 of Regulation No 1107/2009 is the appropriate legal basis for the purposes of including an active substance such as 8-hydroxyquinoline in the list of candidates for substitution. It follows that, for the purposes of the adoption of Article 2 of the contested Implementing Regulation, the procedure described in Articles 7 to 13 of Regulation No 1107/2009 was also applicable under Article 24(2) of that regulation. In those circumstances, the reference made by the contested Implementing Regulation to Article 80(7) of Regulation No 1107/2009 cannot have the effect of depriving the applicant of the procedural rights which it enjoys under Article 24(2) of that regulation, procedural rights which have, moreover, been respected in the present case (see paragraphs 96, 100 and 101 below).

81 It follows from the findings set out in paragraphs 45 to 79 above that the applicant has standing to bring proceedings for the annulment of both Article 1 and Article 2 of the contested Implementing Regulation.

Substance

The first plea in law, alleging infringement of the right to be heard and of the principle of the protection of legitimate expectations

82 The applicant submits that, by failing to examine the studies referred to in paragraph 13 above and by not allowing the applicant effectively to put forward its observations or even participate in an exchange of views on those studies, the Commission infringed the applicant's right to be heard, both in the context of the harmonised classification and labelling procedure closed by the decision of the competent Spanish authority and in that of the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline. First, it argues, those studies were produced with the consent of the competent authority of the rapporteur Member State, under Regulation No 1107/2009, and, second, the procedure for harmonised classification and labelling, in the context of which they were prepared, directly affected the outcome of the procedure for the amendment of the conditions of approval of that active substance.

83 Thus, it argues, contrary to the Commission's submissions, the communication of the studies in question on 31 May 2017 took place within a time scale which enabled that institution to assess the information contained in them which concerns certain crucial scientific issues identified by EFSA in its conclusions under Regulation No 1107/2009 (see paragraph 19 above), as was the case in other similar procedures.

84 Those circumstances, the applicant argues, demonstrate infringement of the principle of the protection of legitimate expectations, since, by their conduct, both the competent Spanish authority and the Commission allowed the applicant to expect them to be aware of the relevance of the studies at issue to both of the pending procedures and that the information relating to those studies would be examined by the Standing Committee. Furthermore, the Commission explicitly stated that that was the case.

85 It should be noted that, in the context of this plea in law, the question arises as to the relationship between the procedure for the amendment of the harmonised classification and labelling of 8-hydroxyquinoline (see paragraphs 11 to 14 above), on the one hand, and the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline (see paragraphs 15 to 25 above), on the other. As stated in those paragraphs, 8-hydroxyquinoline, the active substance approved under Implementing Regulation No 993/2011, also underwent a procedure for harmonised classification and labelling under Regulation No 1272/2008 which resulted in the adoption of Regulation 2017/776 (see paragraph 12 above), under which 8-hydroxyquinoline was classified, inter alia, as toxic in respect of reproduction category 1B. On 20 January 2017, the applicant requested the competent Spanish authority to propose to ECHA the amendment of the harmonised classification and labelling of 8-hydroxyquinoline, stating that the studies referred to in paragraph 13 above had been prepared. That procedure was closed by a letter from the competent Spanish authority of 28 September 2017, in which that authority explained to the applicant the reasons why it had found that the evidence from the studies in question was not sufficient to call into question the harmonised classification and labelling in force and why it therefore did not justify a new proposal in the matter (see paragraph 14 above). By the present plea in law, the applicant claims that, by failing to take account of those studies in the context of the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline, the Commission infringed its right to be heard and the principle of the protection of legitimate expectations.

86 According to Article 41(2)(a) of the Charter of Fundamental Rights of the European Union, the right to good administration includes the right of every person to be heard before any individual measure which would affect him or her adversely is taken. Respect for the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of EU law which must be guaranteed even in the absence of rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they can effectively make known their views on the accusation made against them forming the basis of the contested measure (see, to that effect, judgments of 21 September 2000, *Mediocurso* v *Commission*, C-462/98 P, EU:C:2000:480, paragraphs 36 and 43, and of 1 October 2009, *Foshan Shunde Yongjian Housewares and Hardware* v *Council*, C-141/08 P, EU:C:2009:598, paragraph 83).

87 By contrast, in the case of acts of general application, neither the process of drafting them nor those acts themselves require, in accordance with the general principles of EU law, such as the right to be heard, consulted or informed, the participation of the persons affected. That is not the case if an express provision of the legal context governing the adoption of that act confers a procedural right on a person affected (see, to that effect, orders of 30 September 1997, *Federolio* v *Commission*, T-122/96, EU:T:1997:142, paragraph 75; of 11 September 2007, *Honig-Verband* v *Commission*, T-35/06, EU:T:2007:250, paragraph 45; and judgment of 15 September 2016, *TAO-AFI and SFIE-PE* v *Parliament and Council*, T-456/14, EU:T:2016:493, paragraph 69).

88 As stated in paragraph 48 above, the contested Implementing Regulation establishes measures of general application concerning the conditions of approval of 8-hydroxyquinoline, on the one hand, and the inclusion of that active substance in the list of candidates for substitution, on the other.

89 In that context, the procedural rights which the applicant enjoys in the procedure relating to the amendment of the conditions of approval of 8-hydroxyquinoline are those expressly provided for in Regulation No 1107/2009. Similarly, the procedural rights which the applicant enjoys in the procedure relating to the classification and labelling of that active substance are those expressly provided for in Regulation No 1272/2008.

90 Those regulations govern two distinct matters. In particular, Regulation No 1272/2008 lays down the substantive rules and procedures relating to the classification, labelling and packaging of substances and mixtures. Regulation No 1107/2009, for its part, lays down the substantive rules and procedures for the placing of plant protection products on the market.

91 Although it is true that, as is apparent from Article 4(1) and (7) and Article 24 of, and from points 3.6.4 and 4 of Annex II to, Regulation No 1107/2009, the information arising from the procedure for the harmonised classification and labelling of an active substance may have substantive effects on the approval of that substance, the fact remains that the two procedures are different, each being organised according to its own rules. That conclusion is not called into question by the fact that the proceedings at issue may take place at the same time. Moreover, the fact that the Commission developed, for the purposes of coherence and coordination, a unit model for the submission of evaluation reports in accordance with Regulation No 1107/2009 and for proposals for harmonised classification and labelling in accordance with Regulation No 1272/2008 does not affect the interpretation and application of the procedural rules laid down by those two regulations.

92 As regards the alleged infringement of the applicant's procedural rights in the context of the procedure for the amendment of the harmonised classification and labelling of 8-hydroxyquinoline (see paragraph 11 above), which the applicant appears to allege in paragraphs 75 and 78 of the application, it should be noted that, in the present case, that procedure was closed by virtue of the competent Spanish authority's decision, sent to the applicant by letter of 28 September 2017, not to submit to ECHA a proposal for the amendment of the harmonised classification and labelling in force at the time (see paragraph 14 above).

93 It follows that the Commission did not adopt any act relating to that procedure. It should also be noted that the action seeks the annulment of the contested Implementing Regulation, which concerns the conditions of approval of 8-hydroxyquinoline and was adopted solely under Regulation No 1107/2009. The action cannot therefore be interpreted as relating to the procedure for reviewing the harmonised classification and labelling of the substance in question. Consequently, the applicant cannot successfully rely on an alleged infringement of its right to be heard in the procedure for amendment of the harmonised classification and labelling so as to call into question the legality of the contested Implementing Regulation.

94 As regards the alleged infringement of the applicant's right to be heard in the context of the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline, it should be noted, as the Commission observes, that the applicant's procedural rights in that regard are laid down in Article 12(1) and (2) and Article 13(1) of Regulation No 1107/2009.

95 It is apparent from Article 12(1) of Regulation No 1107/2009 that EFSA is required to circulate the draft assessment report received from the rapporteur Member State, or any addendum thereto, to the applicant and other Member States and is also required to make the draft assessment report available to the public after allowing the applicant to request that certain parts be kept confidential. The applicant and other interested parties may submit their comments on the draft assessment report.

96 As stated in paragraph 16 above, EFSA submitted to the applicant the addendum to the initial draft assessment report for 8-hydroxyquinoline, allowing the applicant 60 days to submit its written observations. The applicant submitted its observations by letter of 9 June 2015 (see paragraph 17 above).

97 Moreover, according to Article 12(2) of Regulation No 1107/2009, within 120 days of the end of the period provided for the submission of written comments, EFSA is required to adopt its conclusions on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation No 1107/2009. Under that provision, EFSA is required to send its conclusions to the applicant, which it did in the present case by letter of 2 May 2016 (see paragraph 19 above).

98 In addition, on 4 September 2015, EFSA had requested the applicant to provide additional information within 90 days, in accordance with Article 12(3) of Regulation No 1107/2009. The applicant acceded to that request by letter of 3 December 2015 (see paragraph 18 above).

99 Article 13(1) of Regulation No 1107/2009, for its part, provides that the applicant may submit its comments on the review report that the Commission presents, taking into account the draft assessment report drawn up by the rapporteur Member State and the conclusions adopted by EFSA.

100 As noted in paragraphs 20 and 21 above, the Commission invited the applicant to submit its observations on the addendum to the review report relating to the application for amendment of the conditions of approval of 8-hydroxyquinoline, which the applicant did on 20 January 2017.

101 Consequently, first, the applicant had the opportunity effectively to submit its observations at each stage of the procedure initiated by its application for amendment of the conditions of approval of 8-hydroxyquinoline in accordance with the time periods laid down in Articles 12 and 13 of Regulation No 1107/2009.

102 Second, as regards the studies referred to in paragraph 13 above, on the one hand, it must be noted that these were not drawn up in the context of the procedure for the amendment of the conditions of approval of 8-hydroxyquinoline, governed by Regulation No 1107/2009, but solely in the context of a proposal to amend the elements of the harmonised classification and labelling of that substance, intended to be submitted to EFSA by the competent Spanish authority in accordance with Article 37 of Regulation No 1272/2008.

103 On the other hand, it is apparent from paragraphs 22 to 24 above that, despite that fact, the Standing Committee, at its meeting of 20 July 2017, postponed the vote on the Commission's proposal for a regulation in that regard.

104 In that respect, it must be recalled that, as is apparent from recitals 6 and 10 of the contested Implementing Regulation, the fact that 8-hydroxyquinoline was to be classified as toxic for reproduction category 1B is the first ground for the refusal to amend the conditions of approval of that active substance (see paragraphs 27 and 29 above). According to point 3.6.4 of Annex II to Regulation No 1107/2009, the fact that an active substance is or has to be classified, in accordance with the provisions of Regulation No 1272/2008, as toxic for reproduction category 1B precludes, in principle, the approval of that substance. That would justify excluding all removal of restrictions associated with the approval of 8-hydroxyquinoline under Implementing Regulation No 993/2011 and limiting its use in greenhouses (see paragraph 3 above). Nevertheless, in so far as the studies produced by the applicant called into question, in its opinion, the scientific bases of that classification, it was open to the Standing Committee to wait until the competent Spanish authority had taken a decision on the applicant's proposal relating to the amendment of the harmonised classification and labelling elements which had been established in the meantime by Regulation 2017/776 (see paragraphs 11 and 12 above). Given that, under that regulation, 8-hydroxyquinoline was classified as toxic for reproduction category 1B, that provisional suspension of the procedure at issue could only benefit the applicant's interests.

105 As is apparent from paragraphs 14, 25 and 26 above, the Standing Committee gave its opinion and the Commission adopted the contested Implementing Regulation on 6 October 2017 and 13 November 2017 respectively, that is to say, after the letter from the competent Spanish authority of

28 September 2017, in which the latter had refused to continue the procedure for the amendment of the harmonised classification and labelling elements. The effect of that refusal was to exclude any procedure for the amendment of Regulation 2017/776 establishing the harmonised classification and labelling elements of 8-hydroxyquinoline, which the Commission was obliged to take into account, in the context of the procedure at issue, under point 3.6.4 of Annex II to Regulation No 1107/2009, for the purposes of the procedure for the amendment of the conditions of approval of that active substance.

106 Third, on the date on which the applicant sent to the Commission the studies referred to in paragraph 13 above, namely on 31 May 2017, no option to submit additional information or observations was available under Articles 12 and 13 of Regulation No 1107/2009. Consequently, even if the studies in question had called into question EFSA's findings relating to the toxic effects of 8-hydroxyquinoline on the endocrine organs, a factor which, according to recital 7 of the contested Implementing Regulation, was the second reason for the refusal to amend the conditions of approval of that active substance (see paragraphs 27 and 29 above), it must be stated that, in view of the case-law cited in paragraph 87 above, the Commission was not required to examine the studies at that stage.

107 It is apparent from the considerations set out in paragraphs 101 to 106 above that the procedure for the adoption of the contested Implementing Regulation is not vitiated by any irregularity capable of constituting an infringement of the applicant's right to be heard in respect of the studies referred to in paragraph 13 above which were sent to the Commission on 31 May 2017.

108 The same applies in regard to the argument based on the alleged infringement of the principle of the protection of legitimate expectations.

109 The principle of the protection of legitimate expectations is one of the fundamental principles of the European Union. The right to rely on that principle assumes that three conditions are satisfied. First, precise, unconditional and consistent assurances originating from authorised and reliable sources must have been given to the person concerned by the administration. Second, those assurances must be such as to give rise to a legitimate expectation on the part of the person to whom they are addressed. Third, the assurances given must comply with the applicable rules (see judgment of 15 July 2015, *Socitrel and Companhia Previdente* v *Commission*, T-413/10 and T-414/10, EU:T:2015:500, paragraph 174 and the case-law cited).

110 It is true that, on 2 June 2017, the Commission stated that the notification that the studies referred to in paragraph 13 above had been sent to the competent Spanish authority would be forwarded to the members of the Standing Committee (see paragraph 23 above). However, that statement does not amount to a precise and unconditional assurance that the studies at issue would form part of the information examined by that committee and by the Commission so that they could take a decision on the application for the amendment of the conditions of approval of 8-hydroxyquinoline independently of the competent Spanish authority's decision on the proposal to amend the harmonised classification and labelling elements. Furthermore, to interpret that statement as providing such assurance would run counter to the Commission's obligation, under point 3.6.4 of Annex II to Regulation No 1107/2009, to take into account the harmonised classification and labelling resulting from the procedure which led to the adoption of Regulation 2017/776. Consequently, the reply which the Commission gave to the applicant on 2 June 2017 can be interpreted, at most, only as an intention to examine the expediency of awaiting the competent Spanish authority's decision on the proposal to amend the harmonised classification and labelling elements before adopting the contested Implementing Regulation. As is apparent from paragraph 105 above, both the Standing Committee and the Commission awaited the competent Spanish authority's decision in that regard.

111 Furthermore, the competent Spanish authority's reference, in its letter of 14 March 2016 (see paragraph 8 above) to Article 62(1) of Regulation No 1107/2009 merely refers to the prudential rules in respect of tests on vertebrate animals and cannot therefore in any way be regarded as providing the applicant with precise assurances, within the meaning of the case-law cited in paragraph 109 above, according to which the Commission decides on the application for amendment of the conditions of approval of 8-hydroxyquinoline without taking account of the harmonised classification and labelling elements established by Regulation 2017/776 and despite the fact that the competent Spanish authority had already refused to implement the proposal to amend the elements in question.

112 It follows that the first plea in law must be rejected.

The second plea in law, alleging a manifest error of assessment

113 According to the applicant, the absence of review of the studies referred to in paragraph 13 above means that the Commission did not examine the question relating to the amendment of the conditions of approval of 8-hydroxyquinoline in the light of current scientific and technical knowledge. In conjunction with the gaps in the information observed in 2015, during the initial procedure for approval of the substance in question, that fact, it contends, constitutes a manifest error of assessment.

114 The Commission disputes those findings.

115 In that regard, it is true that, according to Article 4(1) of Regulation No 1107/2009, an active substance is to be approved in accordance with Annex II to that regulation if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that annex, plant protection products containing that active substance meet the conditions laid down in paragraphs 2 and 3 of that article.

116 However, the procedure according to which relevant scientific and technical knowledge is assessed is set out in Articles 7 to 13 of Regulation No 1107/2009.

117 First, it is apparent from the analysis relating to the first plea that the Commission did not infringe the applicant's right to be heard as regards the taking into account of the studies referred to in paragraph 13 above.

118 Second, as noted in paragraph 104 above, point 3.6.4 of Annex II to Regulation No 1107/2009 requires the Commission to take into account, for the purposes of assessing the application for amendment of the conditions of approval of 8-hydroxyquinoline under Regulation No 1107/2009, the harmonised classification and labelling of that active substance, as they result from the procedure which led to the adoption of Regulation 2017/776.

119 First of all, 8-hydroxyquinoline was classed as toxic for reproduction category 1B under Regulation 2017/776 (see paragraph 12 above), which, according to point 3.6.4 of Annex II to Regulation No 1107/2009, precludes, in principle, the approval of that active substance. Next, by its letter of 28 September 2017, the competent Spanish authority refused to implement the proposal to amend the harmonised classification and labelling elements of 8-hydroxyquinoline (see paragraph 14 above), with the result that the Commission was required to take into account those elements for the purposes of the procedure which led to the adoption of the contested Implementing Regulation. Finally, as is apparent from recital 11 of the contested Implementing Regulation (see paragraph 30 above), the Commission took the view that the administrative procedure at issue could not be classified as a procedure for the review, under Article 21 of Regulation No 1107/2009, of the approval of 8-hydroxyquinoline granted under Implementing Regulation No 993/2011 (see paragraph 2 above), which might even have led to the revocation of that approval. In those circumstances, the

Commission could only reject the application for amendment of the conditions of approval of 8-hydroxyquinoline and confirm the restrictions laid down in Implementing Regulation No 993/2011 (recital 10 of the contested Implementing Regulation).

120 Third, on 31 May 2017, when the applicant submitted to the Commission the studies which it alleges that the Commission failed to take into account, it was not possible to submit additional information or observations under Articles 12 and 13 of Regulation No 1107/2009. In addition, the applicant does not explain how the studies referred to in paragraph 13 above call into question EFSA's conclusions on the toxic effects of 8-hydroxyquinoline on the endocrine organs, conclusions which, according to recital 7 to the contested Implementing Regulation, constitute the second ground for the refusal to amend the conditions of approval of that active substance (see paragraphs 27 and 29 above).

121 It follows that the second plea in law must be rejected.

The third plea in law, alleging infringement of point 4 of Annex II to Regulation No 1107/2009

122 The applicant submits that, by including, pursuant to Article 2 of the contested Implementing Regulation, 8-hydroxyquinoline in the list of candidates for substitution without having first assessed whether human exposure to that active substance was negligible under realistic conditions of use, as required by points 3.6.4 and 3.6.5 of Annex II to Regulation No 1107/2009, the Commission infringed point 4 of Annex II to that regulation.

123 According to the Commission, the sixth and seventh indents of point 4 of Annex II to Regulation No 1107/2009 provide that an approved active substance, which also meets certain alternative conditions, must be included in the list of candidates for substitution. As 8-hydroxyquinoline was approved and meets those conditions, its inclusion in that list, under Article 2 of the contested Implementing Regulation, is not unlawful.

124 According to Article 83 of Regulation No 1107/2009, that regulation repealed Directive 91/414.

125 However, Regulation No 1107/2009 introduced, by Article 80 thereof, a series of transitional provisions. In particular, according to Article 80(1)(c) of Regulation No 1107/2009, Directive 91/414 continued to apply, with respect to the procedure and the conditions for approval, to active substances for which completeness had been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I (OJ 2008 L 15, p. 5).

126 In the present case, as the Commission states in paragraph 9 of the defence, 8-hydroxyquinoline was approved for a period of 10 years under Implementing Regulation No 993/2011 (see paragraph 2 above). It is apparent from recital 1 of that Implementing Regulation that, under the transitional provision of Article 80(1)(c) of Regulation No 1107/2009, 8-hydroxyquinoline was approved in accordance with the substantive conditions laid down in Directive 91/414.

127 According to the sixth indent of point 4 of Annex II to Regulation No 1107/2009, an active substance is to be approved as a candidate for substitution pursuant to Article 24 of that regulation when it is, or is to be, classified as toxic for reproduction category 1A or 1B in accordance with the provisions of Regulation No 1272/2008, but has not been excluded under the criteria defined in point 3.6.4 of Annex II.

128 Moreover, according to the seventh indent of point 4 of Annex II to Regulation No 1107/2009, an active substance is to be approved as a candidate for substitution, pursuant to Article 24 of that regulation, if, on the basis of the assessment of EU or internationally agreed test guidelines or other available data and information, reviewed by EFSA, it is considered to have endocrine-disrupting effects which may cause adverse effects in human beings, but has not been excluded in accordance with the criteria laid down in point 3.6.5 of that Annex II.

129 Finally, points 3.6.4 and 3.6.5 of Annex II to Regulation No 1107/2009 provide that an active substance cannot be approved if it is, or has to be, classified as toxic for reproduction category 1A or 1B or if it is considered to have endocrine-disrupting effects. Those provisions, however, provide for an exception to that rule, in that the substance in question is to be approved despite those characteristics when the exposure of humans to that substance is negligible under realistic conditions of use.

130 It is apparent from the provisions referred to in paragraphs 127 to 129 above that, where an active substance that is toxic for reproduction or has endocrine-disrupting properties is nevertheless approved, either because the conditions for the application of the exception relating to the level of human exposure to the active substance concerned, set out in points 3.6.4 and 3.6.5 of Annex II to Regulation No 1107/2009, have been considered to be met, or because points 3.6.4 and 3.6.5 have not been applied at all, that substance must be included in the list of candidates for substitution.

131 As regards the second situation envisaged in paragraph 130 above, substances which have been approved in accordance with substantive conditions other than those set out in points 3.6.4 and 3.6.5 of Annex II to Regulation No 1107/2009 are to be regarded as substances which have not been excluded under those provisions. Those substances include those which have been approved in accordance with the substantive conditions laid down in Article 5(1) of Directive 91/414.

132 As is apparent from recital 7 of Implementing Regulation No 993/2011, 8-hydroxyquinoline was precisely approved in accordance with the substantive conditions laid down in Article 5(1) of Directive 91/414 under the transitional provision of Article 80(1)(c) of Regulation No 1107/2009 (see paragraph 126 above). It follows that points 3.6.4 and 3.6.5 of Annex II to Regulation No 1107/2009 did not apply during the procedure for the approval of 8-hydroxyquinoline. Furthermore, as is apparent from recitals 5 to 7 of the contested Implementing Regulation, ECHA and EFSA adopted their conclusions on those properties of 8-hydroxyquinoline only in 2015 and 2016 respectively.

133 It follows from the foregoing assessments that, contrary to what the applicant submits, 8-hydroxyquinoline, which was designated as a toxic substance for reproduction category 1B and as having endocrine-disrupting properties, meets one of the two alternative additional conditions set by the provisions of points 3.6.4, 3.6.5 and 4 of Annex II to Regulation No 1107/2009 (see paragraph 130 above) for inclusion in the list of candidates for substitution. As a result, the Commission was required, as it states in recital 12 of the contested Implementing Regulation, to include it in the list of candidates for substitution in accordance with the second paragraph of Article 1 of Implementing Regulation 2015/408, without the need for an examination of the second of the two alternative conditions referred to in paragraph 130 above, relating to the levels of human exposure to that substance under realistic conditions of use.

134 In so doing, the Commission did not therefore infringe Article 4 of Annex II to Regulation No 1107/2009.

135 It must also be observed that, as is apparent from paragraph 129 above, even if the Commission had assessed the level of human exposure to 8-hydroxyquinoline and found that it was negligible, the legal consequence could only have been the inclusion of that active substance in the list of candidates for substitution, that is to say, a situation identical to that resulting from Article 2 of the contested Implementing Regulation. When questioned on that point at the hearing, the applicant did not challenge that analysis, but defended the effectiveness of the third plea in law, arguing that, if the

Commission had undertaken that assessment, that would have delayed the adoption of the contested Implementing Regulation. Since that consideration is manifestly unconnected with the principles governing the interpretation of points 3.6.4, 3.6.5 and 4 of Annex II to Regulation No 1107/2009, it must be held that the third plea in law is, in any event, ineffective.

136 The third plea in law must therefore be rejected, and the action must be dismissed in its entirety.

Costs

137 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Probelte, SA to bear its own costs and to pay those incurred by the European Commission.**

Gratsias Kowalik-Bańczyk Frendo

Delivered in open court in Luxembourg on 19 December 2019.

E. Coulon
Registrar

D. Gratsias
President